

REMARKS:

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, are respectfully requested in light of the remarks which follow.

Support for the amendments to claim 16 can be found, at least, in the specification at page 3, first paragraph.

Priority document

The Office Action has asserted that the European priority document for the subject application is not in the file. However, a certified copy of European Application No. 00114560.6 was filed on October 30, 2001 (see enclosed copy of those filing papers). The Examiner merely needs to retrieve the European priority document from the repository for USPTO papers.

Objection to the claims

As requested by the Examiner, claim 16 has been revised to correct the typographical error. Withdrawal of this objection is therefore requested.

Written description rejection under 35 U.S.C. § 112, first paragraph

Claims 7-10, 16, 18 and 19 were rejected under 35 U.S.C. § 112, first paragraph, as it was alleged that the claims were not supported by an adequate written description. This rejection is traversed.

The Office Action alleged that the claims contained subject matter which was not adequately described in the specification. In particular, it was alleged that there was not an adequate description of the claimed sequences encoding "allelic variants" of MCP-1, and that claim 16 was deficient because it did not "explicitly indicate that the isolated nucleic acid molecule encodes a sequence that has MCP-1 activity." While not conceding as to the propriety of the rejection, claim 16 has been amended in order to expedite prosecution of the subject application. The recitation of "allelic variants" has been deleted, and the claim now recites that the protein encoded by the nucleic acid has "the biological activity of MCP-1."

For at least the above reasons, withdrawal of the written description rejection is believed to be in order.

Enablement rejection under 35 U.S.C. § 112, first paragraph

Claims 7-10, 16, 18 and 19 were rejected under 35 U.S.C. § 112, first paragraph, as it was alleged that the enabling disclosure was not commensurate in scope with the claims. This rejection is also traversed.

The Office Action has asserted that an enabling disclosure has not been provided which is commensurate in scope with the claims. In particular, it has been alleged that the disclosure does not provide enablement for nucleic acid molecules which encode variants which do not have MCP-1 biological activity or a non-isolated host cell comprising the nucleic acid molecule. While not conceding as to the propriety of the rejection, claims 9, 10 and 16 have been amended in order to expedite prosecution of the subject application. The recitation of "allelic variants" has been deleted from claim 16, and claim 16 now recites that the protein encoded by the nucleic acid has "the biological activity of MCP-1." In addition, claims 9 and 10 have been revised to recite "an isolated" recombinant host cell.

For at least the above reasons, withdrawal of the enablement rejection is requested.

Rejection under 35 U.S.C. § 102(b)

Claims 7-10, 16, 18, 19 and 21 were rejected under 35 U.S.C. § 102(b) as being anticipated by Birren et al. (GenBank Accession No. AC005549). This rejection is traversed.

Birren et al. describes a bacterial artificial chromosome (BAC) which contains a 147 kb portion of human chromosome 17. Within the BAC of Birren et al. there appears to be a nucleotide sequence which has some similarity to SEQ ID NO:13 of the present application. However, Birren et al. has no recognition that the BAC contains a nucleotide sequence which encodes MCP-1, or what the proper reading frame might be for any such sequence, or even what strand of the BAC contains a coding sequence for MCP-1. Moreover, Birren et al. has no recognition as to where there might be any regulatory sequences which affect expression of the MCP-1 gene. Hence, Birren et al. could not have guided one to the isolated nucleic acid molecule recited by claim 16.

Claim 16 is even further distinguished over Birren et al by the recitation of an isolated nucleic acid molecule *consisting essentially of* the recited nucleic acid sequences. As recognized by the Office Action, the "consisting essentially of" language excludes subject matter which would materially affect the basic and novel characteristics of the claimed invention. The nucleic acid molecules recited by claim 16 are used, for example, in a

recombinant vector to express the sequence encoding MCP-1. The 147 kb portion of chromosome 17 within the BAC of Birren et al. would not be expected to be useful for such purposes.

More specifically, one would have to perform extensive experiments by treating whole nuclei with DNase I in order to determine which areas of the Birren et al. nucleic acid are in an open chromatin configuration and, hence capable of acting as potential cis-acting transcriptional regulatory sequences. RNA polymerases do not transcribe naked DNA since cellular DNA is packed into nucleosomes as well as interacting with a myriad of different DNA-binding protein. However, the rate of elongation of RNA polymerase II *in vitro* on naked DNA is very similar to the rate measured *in vivo*, inferring that DNA must be cleared of protein during transcription. To allow transcription, nucleosomes must either fall off the DNA template or dissociate temporarily. A useful model is that nucleosomes and DNA are in dynamic association such that changes in local chromatin structure, including post-translational modification of histones, would cause an opening up of the promoter DNA to allow transcription complexes access to the template.

It is clear, however, that DNA which is being actively transcribed is usually in a more "open" chromatin conformation than transcriptionally silent DNA. This phenomenon is demonstrated by DNase I digestion of isolated nuclei. Following digestion, the DNA is separated from chromatin proteins and analysed by gel electrophoresis and Southern blotting, probing for a gene of interest. If a gene is transcriptionally silent it is resistant to DNase I digestion and will be visualised as a high molecular weight band on the Southern blot while transcriptionally active DNA is degraded by the enzyme and lower molecular weight species will be observed. "Open" chromatin contains sites for DNase I digestion that can be two orders of magnitude more sensitive (DNase I-hypersensitive sites) than "bulk" chromatin and these sites are often located in the promoter of a gene. It is likely that these sites reflect opening of chromatin structure induced by binding of transcription factor complexes.

Therefore, without such experiments, the claimed hypersensitive sites cannot be deduced from the sequence information provided by Birren et al., nor would the Birren et al. molecule be expected to be useful for expressing MCP-1. Consequently, the rejection based on Birren et al. is untenable.

Claim 22 even further distinguishes over Birren et al., as it recites a nucleic acid molecule "consisting of" the recited nucleic acid sequences. Thus, this new claim is also patentable over Birren et al.

For at least the above reasons, withdrawal of the § 102 rejection based on Birren et al is requested.

CONCLUSION:

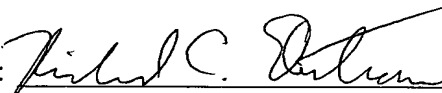
From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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